RRTF

Rodenticide Registrants Task Force

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Via E-Mail

Debra F. Edwards, Ph.D.
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Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Supplemental Information on Issues Discussed During the September 8, 2006, EPA Meeting with the RRTF and NPMA

Dear Dr. Edwards:

On behalf of the Rodenticide Registrants Task Force (RRTF),[1] I am writing to thank you for meeting with Lynn Bergeson and me on September 8, 2006, to discuss the status of the U.S. Environmental Protection Agency's (EPA) risk mitigation measures for rodenticides. Robert Rosenberg of the National Pest Management Association Inc. (NPMA) had scheduled this meeting and graciously invited RRTF representatives to attend.

The RRTF would also like to take this opportunity to provide you with the RRTF's consensus position on rodenticide risk mitigation measures. The consensus position builds upon and expands considerably the measures set forth in the RRTF's Product Stewardship Proposal dated July 20, 2006. As a very important initial matter, and as discussed with EPA on several occasions previously, the RRTF strongly urges EPA to develop separate consumer labeling for rodenticides. The use of consumer labels was also an item that was recommended by the Rodenticide Stakeholder Work Group (RSW) and endorsed by the Pesticide Program Dialogue Committee (PPDC). This initial item is *key* to improving the safety for these products.

[1] Member companies of the RRTF include Bacon Products, Inc., Bell Laboratories, Inc., Farnam Companies, Inc., LiphaTech, Inc., Neogen Corporation, Reckitt Benckiser, Inc., and Syngenta Crop Protection Inc.

Specifically, for consumer rodenticide products: (1) bittering agents would be required; and (2) the use would specify, "For Indoor Use Only" (except for products solely for use in burrow baiting, *e.g.*, mole, gopher burrow baiting). For professional labels: (1) bittering agents would be voluntary; and (2) the use would specify, "For use by a certified applicator and those engaged in farming operations and persons authorized by government-approved pest control programs" (except for products solely for use in burrow baiting, *e.g.*, mole, gopher burrow baiting). Please note that for the professional products to remain available to the end users, professionally labeled products must remain a "General Use" classification.

As set forth below, the RRTF also addresses topics that were of particular interest to EPA staff during the September 8th meeting: (1) the American Association of Poison Control Centers (AAPCC) data on child "exposures" to rodenticides; and (2) the need for and availability of bait stations.

AAPCC Data Illustrate the Remarkably Low Toxicity of Anticoagulant Rodenticides

EPA continues to focus intently on the AAPCC Toxic Exposure Surveillance System data regarding "exposures" to anticoagulant rodenticides (referred to by AAPCC as "superwarfarin"). These data, however, are limited in that they do not differentiate between actual exposures and suspected exposures -- a limitation that the RSW was keenly aware.[2]

The RRTF believes that a considered, careful examination of AAPCC data reveals the remarkably low toxicity and clinical insignificance of unintentional rodenticide exposures. In fact, these data make clear the main concern with rodenticide exposures is not that of adverse health effects but rather that of unnecessary, costly visits to health care facilities and treatment of children ingesting small quantities of rodenticides. This critically important point is borne out by a number of retrospective and prospective studies conducted over the last several years that evaluated the public health significance of AAPCC data.

In a retrospective study of 542 children with superwarfarin exposures published in *Pediatrics*, Dr. Michael Mullins, *et al.*, concluded that "[p]reschool-aged children with single

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2 The RSW (which included the AAPCC) was convened by EPA a number of years ago, in part, to provide EPA with recommendations on managing rodenticide exposures to children in the home. The RSW recommended that EPA not require the use of bittering agents because of expressed concerns that the agent would reduce bait acceptance by targeted rodents.

acute unintentional superwarfarin exposures do not develop any significant laboratory or clinical evidence of excessive anticoagulation. Current guidelines for medical evaluation and repeated laboratory testing in these patients result in unnecessary expenditure. . . . Poison centers and pediatricians should abandon routine evaluation and testing. Parents should receive advice to seek medical attention only in the unlikely occurrence of unusual bleeding or bruising."[3]

Similarly, in a subsequent study published in the *Annals of Emergency Medicine* of 545 children younger than 6 years of age with superwarfarin exposure, Dr. Marianne Ingels, *et al.*, "found no clinically important coagulopathy, even though none of these patients received gastrointestinal decontamination or prophylactic vitamin K. This adds further to the recommendation that children with this type of ingestion may be safely managed at home without gastrointestinal decontamination, prophylactic vitamin K, or routine laboratory testing."[4]

This study's results, coupled with data from other studies, prompted the researchers to amend dramatically the protocol for superwarfarin ingestions at the poison control center where the study was based. "We now recommend no gastric decontamination and no medical treatment or routine laboratory evaluation for pediatric patients with single, acute, unintentional superwarfarin ingestions. . . ."[5]

The largest study conducted to date by Dr. Shepherd, *et al.*, and published in *Pediatric Emergency Care*, reviewed over 10,000 cases of children with single, acute, unintentional ingestions of brodifacoum.[6] According to the researchers, "[a]cute, unintentional pediatric ingestions of brodifacoum . . . rarely produced clinical evidence of morbidity and were not associated with life-threatening symptoms or death. Considering the findings of this study

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3 Mullins, M.E., *et al.* (2000). Unintentional Pediatric Superwarfarin Exposures: Do We Really Need a Prothrombin Time? *Pediatrics* 105:402-404, at 404 (appended).

4 Ingels, M., *et al.* (2002). A Prospective Study of Acute, Unintentional, Pediatric Superwafarin Ingestions Managed Without Decontamination. *Annals of Emergency Medicine* 40(1):73-78, at 76 (hereinafter, A Prospective Study) (appended).

5 *Id.* at 77.

6 Shepherd, G., *et al.* (2002). Acute, unintentional pediatric brodifacoum ingestions. *Pediatric Emergency Care.* 18(3):174-178 (appended).

and previous case series, it seems reasonable that acute, unintentional ingestions of brodifacoum by young children can be adequately managed with home observation and parent education."[7]

Based on the collective weight of these studies, in a 2006 article in *Current Opinion in Pediatrics*, Dr. Dawn Boudrow Kendrick concluded that "[t]here appears to be no benefit in prophylactic vitamin K or gastrointestinal decontamination in patients that have unintentional exposures to a relatively small amount of superwarfarins of less than one box."[8] Dr. Kendrick went on to note that "superwarfarin rodenticides are powerful chemicals that work to protect humans from significant vector-borne diseases. With education and correct usage, these chemicals can help in controlling diseases transmitted to children."[9]

The RRTF wholeheartedly shares Dr. Kendrick's conclusions. The focus should be on educating parents to follow label requirements, rather than treating children unintentionally exposed to rodenticides. In this regard, the RRTF's Product Stewardship Proposal provides a constructive path forward.

It is worth noting that the results of the studies discussed above are even more remarkable in that they are based on exposures to superwarfarin without bittering agents.[10] Moreover, child exposures to rodenticides have fallen 14 percent since 2002; with each passing year since 2002, the number of children exposed to superwarfarin rodenticides has *decreased.*

The RRTF encourages EPA to partner with AAPCC, the American College of Medical Toxicology, the Centers for Disease Control and Prevention, and perhaps other public health organizations, to review the current poison control centers' protocols for assessing children with suspected rodenticide exposures to ensure that children are not undergoing

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7 *Id.* at 177.

8 Kendrick, D.B. (2006). Mosquito repellants and superwarfarin rodenticides -- are they really toxic in children? *Current Opinion in Pediatrics* 18:180-183, at 183 (appended).

9 *Id.*

10 One of the major rodenticide manufacturers recently has begun to add bittering agents to rodenticides, but the impact of this change will not be reflected in the most recent AAPCC report.

needless treatment.[11] The "First Aid" label language for rodenticides may also need to be modified to reflect the current scientific weight of evidence.

Accessibility to Rodenticides Will Be Impeded if EPA Requires That They Be Sold Only with Bait Stations

In a 2003 "Report on Environmental Health Hazards in the Nation's Low Income Housing Stock" (Report), the National Organization of African Americans in Housing (NOAAH)[12] identified rodent and insect infestation as one of "three environmental hazards that pose serious threats to human health in general and disproportionately harm residents of low-income housing." To reduce risks posed by pesticidal use, the Report does not recommend or in any way suggest that rodenticides should be used only with bait stations or that any other additional regulatory requirement is warranted. Instead, the Report appropriately notes that:

> [M]anufacturers typically reduce the risk associated with their products through formulation, application rates and the concentration of the diluted products. . . . Applicators of pesticide products can further reduce the risk of pesticide use by following label directions. Risk can also be significantly reduced by carefully considering the time and site of application. . . . Applying products as directed by the label, and limiting their application to areas of pest activity, further reduces risk and increases the likelihood of solving the pest-management problem.[13]

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11 The RRTF encourages EPA to consult with Dr. Michael Mullins, Assistant Professor of Emergency Medicine at Washington University in St. Louis. He may be reached at (314) 747-5585. Dr. Mullins has extensive knowledge and experience in the area of child exposures to rodenticides.

12 The 2003 Health Homes Initiative (HHI): Report on Environmental Health Hazards in the Nation's Low Income Housing Stock (Feb. 2003).

"NOAAH is an organization that includes housing officials, business people, homeowners, residents, and community leaders who live and work in neighborhood that are most at risk of suffering from the effects of the environmental hazards and threats described in this report." *Id.* at 3.

13 *Id.* at 37.

The Report's emphasis on following label directions dovetails with the RRTF's Product Stewardship Proposal, which, as you know, includes consumer label enhancements and a communication/education campaign.

The RRTF continues to believe that consumers should not be required to purchase bait stations in order to purchase and use rodenticides.[14] This burdensome requirement would merely frustrate consumers' ability to use rodenticides as part of an Integrated Pest Management approach, in which rodenticides play an important role. Residents of low-income housing, who are already disproportionately threatened by human health impacts of pests, would disproportionately bear this burden as well.

The RRTF urges EPA to consider seriously the RRTF's consensus position on risk mitigation measures as well as the additional comments expressed above, as it prepares to issue its draft mitigation decision. The RRTF is hopeful that this forthcoming *Federal Register* notice will enhance both the utility and efficacy of rodenticides -- "that work to protect humans from significant vector-borne diseases."

Sincerely,

John L. Hott

John L. Hott, Ph.D.
Chair

Attachments
cc: Ms. Kelly White Sherman, EPA (w/attachments) (via e-mail)
Lynn L. Bergeson, Esquire (w/attachments) (via e-mail)
David B. Fischer, Esquire (w/attachments) (via e-mail)
Rodenticide Registrants Task Force (w/attachments) (via e-mail)

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14 During our September 8th discussions, EPA staff expressed concern about the lack of availability of bait stations. Although individual retailers may decide not to carry bait stations due to lack of perceived need or shelf space, bait stations are readily accessible through the Internet.